IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DISTRICT

Kimberly Ann Nelson, Plaintiff, v. Johnson & Johnson and Ethicon, Inc., Defendants.	Civil Action No. 3:21-cv-00096 COMPLAINT AND JURY DEMAND

COMPLAINT

COMES NOW Plaintiff, who by and through the undersigned counsel, hereby submits this Complaint and Jury Demand against Johnson & Johnson and Ethicon, Inc. ("Defendants") for compensatory and punitive damages, equitable relief, and such other relief deemed just and proper arising from Plaintiff's injuries from her pelvic mesh implants manufactured by Defendants. In support of this Complaint, Plaintiff alleges the following.

PARTIES

A. Plaintiff

1. Plaintiff Kimberly Ann Nelson ("Ms. Nelson") is a citizen and resident of Dayton, Montgomery County, Ohio.

2. Ms. Nelson was implanted with Ethicon's Gynecare TVT Secur pelvic mesh product, serial no. TVTS4, by Dr. Shelly Joiner at Good Samaritan Hospital in Dayton, Ohio on July 17, 2012. Ms. Nelson was also implanted with Ethicon's Gynecare TVT Exact pelvic mesh product, serial no. TVTRL, by Dr. William Rush at Good Samaritan Hospital in Dayton, Ohio on February 1, 2016.

3. Ms. Nelson subsequently developed complications arising from the implant of the Ethicon pelvic mesh product, including mesh implant complications necessitating removal, worsening mixed incontinence, pelvic pain, dyspareunia, difficulty voiding, stress urinary incontinence, dysuria, frequency, uterine prolapse, nocturia, urinary tract infections, and urgency.

4. All references to "Plaintiff" refer to Kimberly Ann Nelson.

B. Defendants

5. Defendant Johnson & Johnson ("J&J") is a corporation organized and existing under the laws of New Jersey, maintaining its principal place of business at 1 Johnson & Johnson Plaza, New Brunswick, New Jersey 089333. J&J organizes its subsidiary businesses into individual Business Units to coordinate the development, manufacture, testing, marketing promotion, training, distribution and sale of its pelvic floor repair products. Within J&J there are three sectors: medical devices and diagnostics, pharmaceutical, and consumer. Within the medical devices and diagnostic sector are "Business Units" including the "Ethicon Franchise." The Ethicon Franchise was charged by J&J with the design, development, promotion, marketing, testing, training, distribution and sale of the pelvic floor repair products at issue in this case. The Company Group Chairman and Worldwide Franchise Chairman for the Ethicon Franchise, Gary Pruden, is employed by J&J. The companies which comprise the Ethicon Franchise are thus controlled by J&J and include, but are not limited to, Ethicon Inc., Ethicon LLC, Ethicon LTD. J&J is a citizen of New Jersey.

6. Defendant, Ethicon, Inc., is a wholly owned subsidiary of Defendant J&J located in Somerville, New Jersey. Ethicon, Inc. is a corporation organized and existing under New

Jersey law, maintaining its principal place of business at 555 US Route 22, Somerville, New Jersey 08876. Ethicon, Inc. is a citizen of New Jersey.

7. J&J and Ethicon, Inc. are collectively referred to herein as "Ethicon" or "Defendants".

8. All acts and omissions of the above-referenced Defendants as described herein were done by its agents, servants, employees, and/or owners, acting in the course and scope of their respective agencies, services, employments and/or ownership.

JURISDICTION AND VENUE

9. Federal subject matter jurisdiction is based upon 28 U.S.C. § 1332(a), in that there is complete diversity among Plaintiff and Defendants and the amount in controversy exceeds the sum or value of $75,000.00, exclusive of interest and costs.

10. Defendants have significant contacts with this federal judicial district therefore they are subject to the personal jurisdiction of the Court in this district. A substantial part of the events and omissions giving rise to Plaintiff's causes of action occurred in this federal judicial district and therefore, pursuant to 28 U.S.C. § 1391(a), venue is proper in this district.

FACTUAL BACKGROUND

11. Surgical mesh products have been used to repair abdominal hernias since the 1950s. In the 1970s, gynecologists began using surgical mesh products designed for abdominal hernia repair to surgically repair prolapsed organs. In the 1990s, gynecologists began using this surgical mesh for the surgical treatment of pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). Manufacturers, including Defendants, began to modify the mesh used in hernia repair to be used as products specifically intended to correct POP and SUI.

12. A pelvic organ prolapse occurs when a pelvic organ, such as the bladder,

drops ("prolapses") from its normal position and pushes against the walls of the vagina. Prolapse can happen if the muscles that hold the pelvic organs in place become weak or stretched from childbirth or surgery. More than one pelvic organ can prolapse at the same time. Organs that can be involved in a pelvic organ prolapse include the bladder, the uterus, the bowel and the rectum.

13. Defendants' pelvic mesh products are targeted for women who suffer from pelvic organ prolapse and/or stress urinary incontinence as a result of the weakening or damage caused to the walls of the vagina. These products are specifically promoted to physicians and patients as an innovative, minimally invasive procedure with minimal local tissue reactions, minimal tissue trauma and minimal pain while correcting vaginal prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele.

14. Surgical mesh, including mesh used in pelvic mesh products, is a medical device that is generally used to repair weakened or damaged tissue. It is made from porous absorbable or non-absorbable synthetic material or absorbable biologic material. In urogynecologic procedures, surgical mesh is permanently implanted to reinforce the weakened vaginal wall to repair pelvic organ prolapse or to support the urethra to treat urinary incontinence. Most pelvic mesh products are comprised of non-absorbable, synthetic, monofilament polypropylene mesh and/or collagen.

15. Defendants sell pelvic mesh "kits" which can include not only the surgical mesh, but also tissue fixation anchors and insertion tools. The products manufactured by Defendants are considered Class II medical devices.

16. These pelvic mesh products contain polypropylene mesh. Despite claims that this material is inert, the scientific evidence shows that this mesh material is biologically

incompatible with human tissue and promotes an immune response in a large subset of the population receiving Defendants' pelvic mesh products. This immune response promotes degradation of the polypropylene mesh, as well as the pelvic tissue, and can contribute to the formation of severe adverse reactions to the mesh. At all times material, Defendants were aware or had actual knowledge of this information and withheld/omitted and/or misrepresented this information to Plaintiff, Plaintiff's implanting medical providers, the medical community, the FDA, and the public at large.

17. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' pelvic mesh products. This "host defense response" by a woman's pelvic tissues promotes degradation of the polypropylene mesh and the pelvic tissue, and causes chronic inflammation of the pelvic tissue, shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain. It also can cause new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the mesh. At all times material, Defendants were aware or had actual knowledge of this information and withheld/omitted and/or misrepresented this information to Plaintiff, Plaintiff's implanting medical providers, the medical community, the FDA, and the public at large.

18. Furthermore, pelvic mesh products containing collagen cause hyper-inflammatory responses leading to problems including chronic pain and fibrotic reaction.

Defendants' collagen-containing products disintegrate after implantation into the female pelvis. The collagen-containing products cause adverse tissue reactions, and are causally related to infection, as the collagen is a foreign organic material. Cross linked collagen is harsh upon the female pelvic tissues because it hardens the bodily tissues. At all times material, Defendants were aware or had actual knowledge of this information and withheld/omitted and/or misrepresented this information to Plaintiff, Plaintiff's implanting medical providers, the medical community, the FDA, and the public at large.

19. When these pelvic mesh products are inserted in the female body according to the manufacturers' instructions, it creates a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities.

20. In 1996, the FDA cleared the first pelvic mesh products for use in the treatment of stress urinary incontinence (SUI). These products included products manufactured, marketed, and distributed by Defendants. These products were approved by the FDA under the abbreviated 510(k) approval process. Section 510(k) provides for marketing of a medical device if the device is deemed "substantially equivalent" to other predicate devices marketed before May 28, 1976. No formal review for safety or efficacy is required, and no formal review for safety or efficacy was ever conducted with regard to the pelvic mesh products.

21. At various times, Defendants sought and obtained Food and Drug Administration ("FDA") clearance to market the pelvic mesh products under Section 510(k) of the Medical Device Amendment. Section 510(k) allows marketing of medical devices if the device is deemed substantially equivalent to other legally marketed predicate devices marketed prior to May 28, 1976. This clearance process did not require Defendants to prove the safety or efficacy of the pelvic mesh products and, thus, a formal review of the safety and efficacy of the pelvic

mesh products was never conducted with regard to the products.

22. Defendants' pelvic mesh products have been and continue to be marketed to the medical community and directly to patients as safe, effective, reliable medical devices; implanted by safe and effective, minimally invasive surgical techniques for the treatment of medical conditions, primarily vaginal vault prolapse, stress urinary incontinence, pelvic organ prolapse and/or rectocele, and as safer and more effective as compared to the traditional products and procedures for treatment, and other competing pelvic mesh products.

23. The Defendants have marketed and sold the pelvic mesh products to the medical community at large and directly to patients through carefully planned, multifaceted marketing campaigns and strategies. These campaigns and strategies include, but are not limited to, aggressive marketing to health care providers at medical conferences, hospitals, private offices, and include the provision of valuable cash and non-cash benefits to health care providers.

24. Defendants also utilized documents, patient brochures and websites, offering exaggerated and misleading expectations as to the safety and utility of the pelvic mesh products. Defendants further engaged in direct-to-consumer marketing specifically designed to drive consumers to seek out these products for implantation into their bodies.

A. Defendants' Pelvic Mesh Products

25. At all times material to this action, the Defendants were in the business of developing, designing, licensing, manufacturing, distributing, selling, marketing, advertising, and delivering, and introducing into interstate commerce, including, *inter alia*, within the United States, either directly or indirectly through third parties, subsidiaries or related entities, pelvic mesh products.

26. Each of these products was cleared for sale in the United States after the

Defendants made assertions to the Food and Drug Administration of "Substantial Equivalence" under Section 510(k) of the Food, Drug and Cosmetic Act; this clearance process does not require the applicant to prove safety or efficacy.

27. On October 20, 2008, the Food and Drug Administration ("FDA") issued a Public Health Notification that described over 1,000 complaints (otherwise known as "adverse events") that had been reported over a three-year period relating to Pelvic mesh products.

28. Although the FDA notice did not identify the transvaginal mesh manufacturers by name, the FDA's MAUDE database indicates that the Defendants are the manufacturers of pelvic mesh products that are the subject of the notification.

29. On July 13, 2011, the FDA issued a new warning regarding serious complications associated with pelvic mesh products, including the products manufactured, marketed and distributed by Defendants. In this warning, the FDA indicated that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare." (emphasis in the original). The FDA had also received increased reports of complications associated with the pelvic mesh products used in both pelvic organ prolapse and stress urinary incontinence cases.

30. The FDA Safety Communication also stated, "Mesh contraction (shrinkage) is a previously unidentified risk of transvaginal POP repair with mesh that has been reported in the published scientific literature and in adverse event reports to the FDA . . . Reports in the literature associate mesh contraction with vaginal shortening, vaginal tightening and vaginal pain." (emphasis in original).

31. The FDA Safety Communication further indicated that the benefits of using pelvic mesh products instead of other feasible alternatives did not outweigh the associated risks.

Specifically, the FDA Safety Communication stated: "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risks."

32. Contemporaneously with the Safety Communication, the FDA released a publication titled "Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for pelvic Organ Prolapse" (the "White Paper"). In the White Paper, the FDA noted that published, peer-reviewed literature demonstrates that "[p]atients who undergo POP repair with mesh are subject to mesh-related complications that are not experienced by patients who undergo traditional surgery without mesh."

33. The FDA summarized its findings from its review of the adverse event reports and applicable literature stating that it "has NOT seen conclusive evidence that using transvaginally placed mesh in POP repair improves clinical outcomes any more than traditional POP repair that does not use mesh, and it may expose patients to greater risks." (Emphasis in original).

34. The White Paper further stated that "these products are associated with serious adverse events . . . Compounding the concerns regarding adverse events are performance data that fail to demonstrate improved clinical benefit over traditional non-mesh repair." In its White Paper, the FDA advises doctors to, inter alia, "[r]ecognize that in most cases POP can be treated successfully without mesh thus avoiding the risk of mesh related complications." The White Paper concludes by stating that the FDA "has identified serious safety and effectiveness concerns over the use of surgical mesh for the transvaginal repair of pelvic organ prolapse."

35. On August 25, 2011, Public Citizen, a consumer advocacy group, submitted a petition to the FDA seeking to ban the use of pelvic mesh products in pelvic repair procedures.

In its Petition, Public Citizen warned that pelvic mesh products should be recalled because they offer no significant benefits, but expose patients to serious risks and the potential for permanent life-altering harm. Joining Public Citizen as co-petitioners were Dr. L. Lewis Wall, a professor of obstetrics and gynecology at Washington University in St. Louis, and Dr. Daniel S. Elliott, a urologic surgeon specializing in female urology at the Mayo Clinic in Rochester, Minnesota.

36. In a December 2011 Joint Committee Opinion, the American College of Obstetricians and Gynecologists ("ACOG") and the American Urogynecologic Society ("AUGS") also identified physical and mechanical changes to the transvaginal mesh inside the body as a serious complication associated with transvaginal mesh, stating:

> There are increasing reports of vaginal pain associated with changes that can occur with mesh (contraction, retraction, or shrinkage) that result in taut sections of mesh . . . Some of these women will require surgical intervention to correct the condition, and some of the pain appears to be intractable.

37. The ACOG/AUGS Joint Committee Opinion also recommended, among other things, that "[p]elvic organ prolapse vaginal mesh repair should be reserved for high-risk individuals in whom the benefit of mesh placement may justify the risk."

38. As is known to the Defendants, the risks associated with POP repair are the same as SUI repair. However, the data regarding the magnitude and frequency of these known risks are not as developed as the data on POP repair. The FDA recognized this, as demonstrated by its Section 522 Orders issued to manufacturers of pelvic mesh products used to treat SUI in January of 2012.

39. In September 2011, the FDA acknowledged the need for additional data and noted in "Surgical Mesh For Treatment of Women with pelvic Organ Prolapse and Stress Urinary Incontinence" that the literature and information developing on SUI repair with pelvic mesh products "indicate[] that serious complications can occur . . . [and] a case can be made for

additional premarket and/or post market studies to better address the risk/benefit of all mesh products used for SUI."

40. Defendants did not, and have not, adequately studied the extent of the risks associated with the products. In January 2012, the FDA recognized the risk to women and mandated additional studies to further investigate these risks.

41. In 2016, the FDA reclassified Defendants' transvaginal POP products into Class III or high risk.

42. On April 16, 2019, the FDA ordered all transvaginal POP device manufacturers, including Defendants, to stop selling and distributing these products immediately. The FDA had not received sufficient evidence to assure that the probable benefits of these devices outweighed their probable risks, and concluded that these products do not have a reasonable assurance of safety and effectiveness.

43. Defendants knew or should have known that the products unreasonably exposed patients to the risk of serious harm while conferring no benefit over available feasible alternatives that do not involve the same risks. At the time Defendants began marketing each of their pelvic mesh products, Defendants were aware that their pelvic mesh products were associated with each and every one of the adverse events communicated by the FDA in its July 13, 2011, safety communication. Despite claims that polypropylene mesh is inert, the scientific evidence shows that this material as implanted in the Plaintiff is biologically incompatible with human tissue and when used as a woven or knitted alloplastic textile prosthetic mesh for pelvic floor repair, polypropylene and other surgical polymers promote a severe foreign body reaction and chronic inflammatory response in a large subset of the population implanted with Defendants' pelvic mesh products. This "host defense response" by a woman's pelvic tissues

promotes degradation of the polypropylene mesh and the pelvic tissue, causes chronic inflammation of the pelvic tissue, causes shrinkage or contraction of the mesh leading to nerve entrapment, further inflammation, chronic infectious response and chronic pain, causes new-onset painful sexual relations, significant urinary dysfunction, vaginal shortening and anatomic deformation, and can contribute to the formation of severe adverse reactions to the polypropylene mesh.

44. The FDA defines both "degradation" and "fragmentation" as "device problems" to which the FDA assigns a specific "device problem code." "Material Fragmentation" is defined as an "[i]ssue associated with small pieces of the device breaking off unexpectedly" and "degraded" as an "[i]ssue associated with a deleterious change in the chemical structure, physical properties, or appearance in the materials that are used in device construction."

45. Defendants knew or should have known about the pelvic mesh products' risks and complications identified in the FDA Safety Communications and the ACOG/AUGS Joint Committee Opinion.

46. Defendants also knew or should have known that: (1) some of the predicate products for the pelvic mesh products had high failure and complication rates, resulting in the recall of some of these predicate devices (including a medical device known as the Protogen device); (2) that there were and are differences between the Defendants' pelvic mesh products and some or all of the predicate products, rendering them unsuitable for designation as predicate products; (3) that significant differences exist and existed between the pelvic mesh products and their predecessor and predicate products, such that the disclosures to the FDA were and are incomplete and misleading; and (4) that the pelvic mesh products were and are causing numerous patients severe injuries and complications.

47. The Defendants suppressed this information and failed to accurately and completely disseminate or share this and other critical information with the FDA, health care providers and the patients. As a result, the Defendants actively and intentionally misled and continue to mislead the public, including the medical community, health care providers and patients, into believing that the pelvic mesh products and the procedures for implantation were and are safe and effective, leading to the prescription for and implantation of the pelvic mesh products into Plaintiff.

48. Defendants also failed to perform or rely on proper and adequate testing and research in order to determine and evaluate the risks and benefits of their pelvic mesh products. Defendants' above-referenced failures continue to this day.

49. Defendants failed to design and establish a safe, effective procedure for removal of the pelvic mesh products. Therefore, in the event of a failure, injury, or complications, it is impossible to easily and safely remove the pelvic mesh products. Defendants' above-referenced failures continue to this day.

50. Feasible and suitable alternative designs as well as suitable alternative procedures and instruments for implantation have existed at all times relevant as compared to the Defendants' pelvic mesh products.

51. The pelvic mesh products were at all times utilized and implanted in a manner foreseeable to the Defendants, as Defendants generated the instructions for use, created the procedures for implanting the devices and trained the implanting physicians.

52. Furthermore, the Defendants provided incomplete, insufficient and misleading training and information to physicians, in order to increase the number of physicians utilizing their pelvic mesh products, and thus increase the sales of the pelvic mesh products, and also

leading to the dissemination of inadequate and misleading information to patients, including Plaintiff. Defendants' above-referenced failures continue to this day.

53. To this day, the Defendants' pelvic mesh products continue to be marketed to the medical community and to patients as safe, effective and reliable medical devices, implanted by safe, effective and minimally invasive surgical techniques, and as safer and more effective as compared to available feasible alternative treatments of pelvic organ prolapse and/or stress urinary incontinence and other competing products.

54. Defendants misrepresented, omitted and downplayed the known risks, dangers, adverse events, contraindications, defects and disadvantages of the products, and advertised, promoted, marketed, sold and distributed the products as safe medical devices when Defendants knew or should have known that the products were not safe for their intended purposes, and that the products would cause, and did cause, serious medical problems, and in some patients, including the Plaintiff, catastrophic injuries. Further, while some of the problems associated with the products were made known to physicians, the magnitude and frequency of these problems were not disclosed and were hidden from physicians.

55. Contrary to Defendants' representations and marketing to the medical community and to the patients themselves, the products have high rates of failure, injury, and complications, fail to perform as intended, require frequent and often debilitating re-operations, and have caused severe and irreversible injuries, conditions, and damage to a significant number of women, including the Plaintiff, making them defective under the law.

56. The specific nature of the products' defects include, but are not limited to, the following:

a. the use of polypropylene in the products and the adverse tissue

reactions and host defense response that result from such material, causing adverse reactions and serious, permanent injuries including, but not limited to, painful recurrent erosions and associated intractable pain;

b. the design of the products to be inserted into and through an area of the body that is blood vessel rich, nerve dense, and bacteria laden leading to excessive blood loss and vascular damage, permanent nerve injury and associated chronic, intractable neuropathic pain, contaminated permanently-implanted mesh causing chronic infections, subclinical infections and biofilms, enhanced chronic inflammatory response, chronic wound healing with tissue destruction, as well as numerous other adverse reactions and serious and permanent injuries;

c. biomechanical issues with the design of the products which result in a non-anatomic condition leading to contraction or shrinkage of the mesh inside the body, that in turn causes surrounding tissue to become eroded, inflamed, fibrotic and infected, resulting in serious and permanent injury;

d. the propensity of the mesh design characteristics of the products for plastic deformation when subjected to tension both during implantation and once implanted inside the body which causes the mesh, or portions thereof, to be encapsulated in a rigid scar plate which leads to nerve entrapment, bacterial entrapment, tissue destruction, enhanced inflammatory and fibrotic response and chronic pain;

e. the propensity of the products to become rigid and inflexible, causing

them to be improperly mated to the delicate and sensitive areas of the vagina and pelvis where they are implanted, and causing discomfort and pain with normal daily activities that involve movement in the pelvic region (e.g., intercourse, defecation, walking);

f. the propensity of the products for degradation or fragmentation over time, which causes an increased surface area that leads to enhanced chronic inflammatory and fibrotic reaction, causes a "barbed wire" or "saw blade" effect by the fragmented surface "sawing" through the tissue, leads to bacteria harboring in the fragmented, peeled and split fiber surface which in turn leads to chronic infections at the mesh surface, and results in continuing injury over time;

g. the hyper-inflammatory responses to collagen leading to problems including chronic inflammatory response, chronic pain and fibrotic reaction as well as infections and other serious adverse events;

h. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

i. the harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

j. the inability of surgeons to effectively treat many of these conditions due to the integration of the mesh into the pelvic tissue and thus the inability to safely remove or excise the mesh once a complication occurs.

57. The products are also defective due to Defendants' failure to adequately

warn or instruct the Plaintiff and/or their health care providers of known subjects including, but not limited to, the following:

a. the products' propensities to contract, retract, and/or shrink inside the body;

b. the products' propensities for degradation, fragmentation and/or migration;

c. the products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the frequency and manner of transvaginal mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the products;

f. the risk of chronic infections resulting from the products;

g. the risk of permanent vaginal or pelvic scarring as a result of the products;

h. the risk of de novo urinary dysfunction;

i. the risk of de novo dyspareunia or painful sexual relations;

j. the risk of recurrent, intractable pelvic pain and other pain resulting from the products;

k. the need for corrective or revision surgery to adjust or remove the products which in some cases is not feasible nor possible;

l. the severity of complications that could arise as a result of implantation of the products;

m. the hazards associated with the products;

n. the products' defects described herein;

o. treatment of pelvic organ prolapse and stress urinary incontinence with

the products is no more effective than feasible, available and safer alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the products exposes patients to greater risk than feasible, available and safer alternatives;

q. treatment of pelvic organ prolapse and stress urinary incontinence with the products makes future surgical repair more difficult than feasible, available and safer alternatives;

r. use of the products puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. removal of the products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life; and

t. complete removal of the products may not be possible and may not result in complete resolution of the complications, including pain.

CAUSES OF ACTION

COUNT I
NEGLIGENCE

58. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

59. Defendants had a duty to individuals, including the Plaintiff, to use reasonable care in designing, researching, manufacturing, marketing, labeling, packaging, supplying, distributing and selling the pelvic mesh products.

60. Defendants were negligent in failing to use reasonable care as described herein in designing, manufacturing, marketing, labeling, packaging and selling the products.

Defendants breached their aforementioned duty by:

a. failing to design the products so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including the Plaintiff;

b. failing to manufacture the products so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including the Plaintiff;

c. failing to use reasonable care in the testing of the products so as to avoid an unreasonable risk of harm to women in whom the products were implanted, including the Plaintiff;

d. failing to use reasonable care in inspecting the products to avoid an unreasonable risk of harm to women in whom the products were implanted, including the Plaintiff; and

e. otherwise negligently or carelessly designing, manufacturing, marketing, labeling, packaging and/or selling the products.

61. The reasons that Defendants' negligence caused the products to be unreasonably dangerous and defective include, but are not limited to:

a. the use of polypropylene material in the products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and

injuries;

c. biomechanical issues with the design of the products, including, but not limited to, the propensity of the products to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the products, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the products for migration or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in the pelvis (e.g., intercourse, defecation);

g. the propensity of the products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the propensity of the products to cause long standing inflammatory response altering the effective porosity of the mesh resulting in poor outcomes including bridging fibrosis, compromise of tissues in contact with or surrounding the mesh, erosion, nerve damage and resulting neuromas; and

i. the creation of a non-anatomic condition in the pelvis leading to chronic

pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

62. Defendants also negligently failed to warn or instruct the Plaintiff and/or her health care providers of known subjects including, but not limited to, the following:

a. the products' propensities to contract, retract and/or shrink inside the body;

b. the products' propensities for degradation, fragmentation and/or migration;

c. the products' inelasticity preventing proper mating with the pelvic floor and vaginal region;

d. the frequency and manner of mesh erosion or extrusion;

e. the risk of chronic inflammation resulting from the products;

f. the risk of chronic infections resulting from the products;

g. the risk of permanent vaginal or pelvic scarring as a result of the products;

h. the risk of de novo urinary dysfunction;

i. the risk of de novo dyspareunia or painful sexual relations;

j. the risk of recurrent, intractable pelvic pain and other pain resulting from the products;

k. the need for corrective or revision surgery to adjust or remove the products which in some cases is not feasible nor possible;

l. the severity of complications that could arise as a result of implantation of the products;

m. the hazards associated with the products;

n. the products' defects described herein;

o. treatment of pelvic organ prolapse and stress urinary incontinence with the products is no more effective than feasible, available and safer alternatives;

p. treatment of pelvic organ prolapse and stress urinary incontinence with the products exposes patients to greater risk than feasible, available and safer alternatives;

q. treatment of pelvic organ prolapse and stress urinary incontinence with the products makes future surgical repair more difficult than feasible, available and safer alternatives;

r. use of the products puts the patient at greater risk of requiring additional surgery than feasible, available and safer alternatives;

s. removal of the products due to complications may involve multiple surgeries and may significantly impair the patient's quality of life;

t. complete removal of the products may not be possible and may not result in complete resolution of the complications, including pain; and

u. as a result of these life-altering and, in some cases, permanent injuries, Plaintiff has suffered severe emotional pain and injury and has suffered and will suffer apprehension of increased risk for injuries, infections, pain, mental anguish, discharge and multiple corrective surgeries as a result of implantation of mesh.

63. Defendants likewise failed to conduct post-market vigilance or surveillance by:

a. monitoring or acting on findings in the scientific and medical literature;

b. monitoring or investigating and evaluating reports in the FDA adverse event databases for their potential significance for Defendants' pelvic mesh products;

c. failing to comply with manufacturer requirements of the medical device; and

d. reporting (MDR) Regulations, specifically:

i. Failing to report MDRs (Medical Device [adverse event] Reports); and

ii. failing to investigate reports of serious adverse events.

64. As a direct and proximate result of Defendants' negligence, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

65. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT II
STRICT LIABILITY-DESIGN DEFECT

66. Plaintiff incorporates by reference each and every paragraph of this Complaint

as if fully set forth herein.

67. The product implanted in Plaintiff was not reasonably safe for its intended use and was defective as described herein with respect to its design. As previously stated, these products' design defects include, but are not limited to:

a. the use of polypropylene material and/or collagen material in the products and the immune reaction that results from such material, causing adverse reactions and injuries;

b. the design of the products to be inserted into and through an area of the body with high levels of bacteria that adhere to the mesh causing immune reactions and subsequent tissue breakdown and adverse reactions and injuries;

c. biomechanical issues with the design of the product, including, but not limited to, the propensity of the product to contract or shrink inside the body, that in turn cause surrounding tissue to be inflamed, become fibrotic, and contract, resulting in injury;

d. the use and design of arms and anchors in the product, which, when placed in the women, are likely to pass through contaminated spaces and injure major nerve routes in the pelvic region;

e. the propensity of the products for migration or to gradually elongate and deform when subject to prolonged tension inside the body;

f. the inelasticity of the products, causing them to be improperly mated to the delicate and sensitive areas of the pelvis where they are implanted, and causing pain upon normal daily activities that involve movement in

the pelvis (e.g., intercourse, defecation);

g. the propensity of the products for degradation or fragmentation over time, which causes a chronic inflammatory and fibrotic reaction, and results in continuing injury over time;

h. the hyper-inflammatory responses to collagen leading to problems including chronic pain and fibrotic reaction;

i. the propensity of the collagen products to disintegrate after implantation in the female pelvis, causing pain and other adverse reactions;

j. the adverse tissue reactions caused by the collagen products, which are causally related to infection, as the collagen is a foreign organic material;

k. the harshness of collagen upon the female pelvic tissue, and the hardening of the product in the body; and

l. the creation of a non-anatomic condition in the pelvis leading to chronic pain and functional disabilities when the mesh is implanting according to the manufacturers' instructions.

68. As a direct and proximate result of the product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo future medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, lost income, and other damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

69. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

70. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT III
STRICT LIABILITY – MANUFACTURING DEFECT

71. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

72. The product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law with respect to its manufacture, in that it deviated materially from Defendants' design and manufacturing specifications in such a manner as to pose unreasonable risks of serious bodily harm to the Plaintiff.

73. As a direct and proximate result of the product's aforementioned defects as described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and corrective surgery and hospitalization, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

74. Defendants are strictly liable to the Plaintiff named in this Complaint for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

75. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IV
STRICT LIABILITY – FAILURE TO WARN

76. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

77. The product implanted in the Plaintiff was not reasonably safe for its intended use and was defective as described herein as a matter of law due to its lack of appropriate and necessary warnings. Specifically, Defendants did not provide sufficient or adequate warnings to the Plaintiff, her medical providers, the medical community, the FDA, and/or public at large.

78. Defendants were and are aware that their products, as described herein, degrade, contract, shrink, fray, cord, migrate, stiffen, loose pore size with tension, and/or otherwise deform at all times relevant to Plaintiff's claims.

79. Defendants have a post-implant and continuing duty to warn Plaintiff, her medical providers, the medical community, the FDA, and/or the public at large of their products' known characteristics or defective propensities as described herein. Defendants breached and continue to breach these duties owed to Plaintiff, her medical providers, the medical community, the FDA, and/or the public. These duties are continuing in nature and will only expire until Defendants permanently remove their products from the market, all medical providers cease implanting Defendants pelvic products into their patients, and/or the FDA bans said products from the market, each of which has yet to occur.

80. As a direct and proximate result of the products' aforementioned defects as

described herein, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

81. Defendants are strictly liable to the Plaintiff for designing, manufacturing, marketing, labeling, packaging and selling a defective product.

82. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT V
STRICT LIABILITY – DEFECTIVE PRODUCT

83. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

84. At the time of Plaintiff's injuries, the Defendants' pelvic mesh products were defective and unreasonably dangerous to foreseeable consumers, patients, and users, including Plaintiff, and the warnings, labels, and instructions were deficient.

85. The Defendants' pelvic mesh products are dangerous and defective, unfit and unsafe for their intended and reasonably foreseeable uses, and do not meet or perform to the expectations of patients and their health care providers.

86. Plaintiff bring strict product liability claims under the common law, Section

402A of the Restatement of Torts (Second) against Defendants.

87. As a proximate result of the Defendants' design, manufacture, marketing, sale and distribution of the pelvic mesh products, Plaintiff has been injured and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

88. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VI
BREACH OF EXPRESS WARRANTY

89. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

90. Defendants made assurances as described herein to the general public, hospitals and health care professionals that the pelvic mesh products were safe and reasonably fit for their intended purposes.

91. The Plaintiff and/or her healthcare providers chose the product based upon Defendants' warranties and representations, as described herein, regarding the safety and fitness of their products.

92. The Plaintiff, individually and/or by and through her physicians as her agents, reasonably relied upon Defendants' express warranties and guarantees that the products were

safe, merchantable, and reasonably fit for their intended purposes.

93. Defendants breached these express warranties because the product implanted in the Plaintiff was unreasonably dangerous and defective, as described herein, and not as Defendants had represented.

94. Defendants' breach of their express warranties resulted in the implantation of unreasonably dangerous and defective product in Plaintiff, placing Plaintiff's health and safety in jeopardy.

95. As a direct and proximate result of Defendants' breach of the aforementioned express warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

96. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VII
BREACH OF IMPLIED WARRANTY

97. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

98. Defendants impliedly warranted that the pelvic mesh products were

merchantable and were fit for the ordinary purposes for which they were intended.

99. When the product was implanted in the Plaintiff to treat her stress urinary incontinence and/or pelvic organ prolapse, the product was being used for the ordinary purpose for which it was intended.

100. The Plaintiff, individually and/or by and through her physicians as her agents, relied upon Defendants' implied warranties of merchantability in consenting to have the product implanted in her.

101. Defendants breached these implied warranties of merchantability because the product implanted in the Plaintiff was neither merchantable nor suited for its intended use as warranted.

102. Defendants' breach of their implied warranties resulted in the implantation of unreasonably dangerous and defective product in Plaintiff, placing Plaintiff's health and safety in jeopardy.

103. As a direct and proximate result of Defendants' breach of the aforementioned implied warranties, the Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to, obligations for medical services and expenses, and/or lost income, and other damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

104. WHEREFORE, Plaintiff demands judgment against Defendants, and each of

them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT VIII
FRAUDULENT CONCEALMENT

105. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

106. Throughout the relevant time periods, it was known or knowable to Defendants that their pelvic mesh products caused large numbers of complications that were not rare. Moreover, it was known or knowable to Defendants that the surgical technique and training of implanting physicians was not the cause of the adverse events associated with these devices. It was known or knowable to Defendants that the safety and efficacy of their pelvic mesh products had not been proven with respect to, among other things, the product, their components, their performance and their method of insertion. It was known or knowable to Defendants that there was no evidence that their pelvic mesh products were safe and effective and, in fact the evidence that was known or knowable to Defendants was that their pelvic mesh products were not safe and effective. Defendants continued to represent that their pelvic mesh products were safe and effective.

107. Despite what was known or knowable to Defendants about the lack of safety and efficacy of their pelvic mesh products through the relevant time periods, Defendants failed to disclose this information to the Plaintiff, to their physicians or to the public at large.

108. Despite this knowledge, Defendants continued to market and sell their pelvic mesh products and procedures as being safe and efficacious with evidence to the contrary. Additionally, Defendants wrongfully and intentionally, through their physician training program,

provided physicians with the comfort that they had sufficient training, consistent with the 2008 FDA PHN, to minimize or eliminate adverse effects resulting from the devices.

109. At all times mentioned herein, Defendants, and each of them, had the duty and obligation to disclose to Plaintiff and to their physicians, the true facts concerning the aforesaid products, that is, that said products were dangerous and defective, lacking efficacy for their purported use and lacking safety in normal use, and how likely it was to cause serious consequences to users including permanent and debilitating injuries. Defendants concealed these material facts prior to the time that Plaintiff were implanted with Defendants' pelvic mesh products.

110. Defendants were under a duty to Plaintiff to disclose and warn of the defective nature of the products because:

a. Defendants were in a superior position to know the true quality, safety and efficacy of the Defendants' pelvic mesh products;

b. Defendants knowingly made false claims about the safety and quality of the Defendants' pelvic mesh products in the documents and marketing materials Defendants provided to the FDA, physicians, and the general public; and

c. Defendants fraudulently and affirmatively concealed the defective nature of the Defendants' pelvic mesh products from Plaintiff.

111. The facts concealed and/or not disclosed by Defendants to Plaintiff were material facts that a reasonable person would have considered to be important in deciding whether or not to purchase and/or use the Defendants' pelvic mesh products.

112. At all times herein mentioned, Defendants, and each of them, willfully,

intentionally, and maliciously concealed facts as set forth above from Plaintiff and her physicians, and as a result Plaintiff, with the intent to defraud as herein alleged.

113. Defendants intentionally concealed and/or failed to disclose the true defective nature of the products so that Plaintiff would request and purchase the Defendants' pelvic mesh product, and that her healthcare providers would dispense, prescribe, and recommend the Defendants' pelvic mesh products, and Plaintiff justifiably acted or relied upon, to her detriment, the concealed and/or non-disclosed facts as evidenced by her purchase of the Defendants' pelvic mesh product.

114. At all times herein mentioned, neither Plaintiff nor her physicians were aware of the facts set forth above, and had they been aware of said facts, they would not have acted as they did, that is, would not reasonably relied upon said representations of safety and efficacy and utilized the pelvic mesh product for treatment of stress urinary incontinence.

115. To this day, Defendants continue to intentionally conceal and/or fail to disclose the true defective nature of their products, as indicated above.

116. Defendants' failure to disclose this information was a substantial factor in Plaintiff's physicians selecting Defendants' pelvic mesh products and procedures for treatment of stress urinary incontinence and pelvic organ prolapse. This failure to disclose also resulted in the provision of incorrect and incomplete information to the Plaintiff as a patient. As a direct and proximate result of this conduct, Plaintiff was injured. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

117. WHEREFORE, Plaintiff demands judgment against Defendants, and each of

them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT IX
CONSTRUCTIVE FRAUD

118. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

119. Defendants are in a unique position of knowledge concerning the quality, safety and efficacy of the Defendants' pelvic mesh products, which knowledge is not possessed by Plaintiff or her physicians, and Defendants thereby hold a position of superiority over Plaintiff and her physicians.

120. Despite their unique and superior knowledge regarding the defective nature of the Defendants' pelvic mesh products, Defendants continue to suppress, conceal, omit, and/or misrepresent information to Plaintiff, the medical community, and/or the FDA, concerning the severity of risks and the dangers inherent in the intended use of the Defendants' pelvic mesh products, as compared to other products and forms of treatment.

121. Defendants have concealed and suppressed the above-referenced material information, including limited clinical testing, that would reveal that the Defendants' pelvic mesh products had a higher risk of adverse effects, in addition to, and exceeding those associated with alternative procedures and available devices. Instead, Defendants have misrepresented the safety and efficacy of their products.

122. Upon information and belief, Defendants' misrepresentations are and were designed to induce physicians and Plaintiff to prescribe, dispense, recommend and/or purchase the Defendants' pelvic mesh products. Plaintiff and the medical community have relied upon

Defendants' representations.

123. Defendants took unconscionable advantage of their dominant position of knowledge with regard to Plaintiff and her medical providers and engaged in constructive fraud in their relationship with Plaintiff and her medical providers. Plaintiff reasonably relied on Defendants' representations.

124. As a proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

125. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT X
DISCOVERY RULE, TOLLING AND FRAUDULENT CONCEALMENT

126. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

127. Plaintiff asserts all applicable state statutory and common law rights and theories related to the tolling or extension of any applicable statute of limitations, including equitable tolling, delayed discovery, discovery rule, and fraudulent concealment.

128. Plaintiff pleads that the discovery rule should be applied to toll the running of the statute of limitations until Plaintiff knew, or through the exercise of reasonable care and

diligence should have known, of facts indicating that Plaintiff had been injured, the cause of the injury and the tortious nature of the wrongdoing that caused the injury.

129. Despite diligent investigation by Plaintiff into the cause of her injuries, including consultations with Plaintiff's medical providers, the nature of Plaintiff's injuries and damages, and their relationship to the products was not discovered, and through reasonable care and due diligence could not has been discovered, until a date within the applicable statute of limitations for filing Plaintiff's claims. Therefore, under appropriate application of the discovery rule, Plaintiff's suit was filed well within the applicable statutory limitations period.

130. The running of the statute of limitations in this cause is tolled due to equitable tolling. Defendants are estopped from asserting a statute of limitations defense due to Defendants' fraudulent concealment, through past and continuing affirmative misrepresentations and omissions, from Plaintiff and Plaintiff's physicians of the true risks associated with the products. As a result of Defendants' fraudulent concealment, Plaintiff and Plaintiff's physicians were unaware, and could not have known or have learned through reasonable diligence that Plaintiff had been exposed to the risks alleged herein and that those risks were the direct and proximate result of the wrongful acts and omissions of the Defendants.

COUNT XI
NEGLIGENT MISREPRESENTATION

131. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

132. Defendants had and have a duty to accurately and truthfully represent to the medical and healthcare community, Plaintiff, the FDA, and the public, that the pelvic mesh products had not been adequately tested and found to be safe and effective for the treatment of incontinence and/or prolapse. The representations made by Defendants, in fact, were false.

133. Defendants failed to exercise ordinary care in the representations concerning the pelvic mesh products while they were involved in their manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because Defendants negligently misrepresented the pelvic mesh products' high risk of unreasonable, dangerous, adverse side effects. Defendants' above-referenced failures continue to this day.

134. Defendants breached their duty in representing that the Defendants' pelvic mesh products have no serious side effects different from older generations of similar products and/or procedures to Plaintiff, Plaintiff's physicians, and the medical and healthcare community. Defendants' above-referenced breaches continue to this day.

135. As a foreseeable, direct and proximate result of the negligent misrepresentation of Defendants as set forth herein, Defendants knew, and had reason to know, that the pelvic mesh products had been insufficiently tested, or had not been tested at all, and that they lacked adequate and accurate warnings, and that they created a high risk, and/or higher than acceptable risk, and/or higher than reported and represented risk, of adverse side effects, including, erosion, pain and suffering, surgery to remove the products, and other severe and personal injuries, which are permanent and lasting in nature. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

136. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort and economic damages.

137. WHEREFORE, Plaintiff demands judgment against Defendants, and each of

them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XII
NEGLIGENT INFLICTION OF EMOTIONAL DISTRESS

138. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

139. Defendants carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' pelvic mesh product to Plaintiff, carelessly and negligently concealing the harmful effects of the Defendants' pelvic mesh product from Plaintiff, and carelessly and negligently misrepresented the quality, safety and efficacy of the product.

140. Plaintiff was directly impacted by Defendants' carelessness and negligence, in that Plaintiff has sustained and will continue to sustain emotional distress, severe physical injuries, economic losses, and other damages as a direct result of being implanted with the pelvic mesh product sold and distributed by Defendants and/or because of the nature of their relationship to the individual implanted with the pelvic mesh product.

141. As a direct and proximate result of the Defendants' conduct, Plaintiff has been injured, and sustained severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and economic damages. As long as parts of Defendants' pelvic mesh product remain implanted in Plaintiff or Plaintiff experienced permanent injuries caused by Defendants' device before removal, Plaintiff will continue to suffer the above-referenced and new injuries until death.

142. WHEREFORE, Plaintiff demands judgment against Defendants, and each of

them, individually, jointly, severally and in the alternative, and request compensatory damages, punitive damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XIII
VIOLATION OF OHIO CONSUMER PROTECTION ACT

143. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

144. Plaintiff purchased and used the Defendants' pelvic mesh product primarily for personal use and thereby suffered ascertainable losses as a result of Defendants' actions in violation of the Ohio Consumer Sales Practices Act, Ohio Rev. Code §1345.01 et. Seq. ("The Act").

145. Had Defendants not engaged in the deceptive conduct described herein, Plaintiff would not have purchased and/or paid for the Defendants' pelvic mesh product, and would not have incurred related medical costs and injury.

146. Defendants engaged in wrongful conduct while at the same time obtaining, under false pretenses, monies from Plaintiff for the pelvic mesh product that would not have been paid had Defendants not engaged in unfair and deceptive conduct.

147. Unfair methods of competition or deceptive acts or practices that were proscribed by law, including the following:

a. representing that goods or services have characteristics, ingredients, uses benefits or quantities that they do not have;

b. advertising goods or services with the intent not to sell them as advertised; and

c. engaging in fraudulent or deceptive conduct that creates a likelihood of

confusion or misunderstanding.

148. Plaintiff was injured by the cumulative and indivisible nature of Defendants' conduct. The cumulative effect of Defendants' conduct directed at patients, physicians and consumers was to create demand for and sell the Defendants' pelvic mesh products. Each aspect of Defendants' conduct combined to artificially create sales of the Defendants' pelvic mesh products.

149. Defendants have a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion and sale of the Defendants' pelvic mesh products.

150. Had Defendants not engaged in the deceptive conduct described above, Plaintiff would not have purchased and/or paid for the product, and would not have incurred related medical costs.

151. Defendants' deceptive, unconscionable, or fraudulent representations and material omissions to patients, physicians and consumers, including Plaintiff, constituted unfair and deceptive acts and trade practices in violation of The Act.

152. Defendants' actions, as complained of herein, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of The Act.

153. Defendants have engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations in violation of The Act.

154. Under The Act, which protects consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, Defendants are the suppliers, manufacturers, advertisers, and sellers, who are subject to liability under such

legislation for unfair, deceptive, fraudulent and unconscionable consumer sales practices.

155. Defendants violated The Act which was enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising, by knowingly and falsely representing that the Defendants' pelvic mesh products were fit to be used for the purpose for which they were intended, when in fact they were defective and dangerous, and by other acts alleged herein. These representations were made in marketing and promotional materials.

156. The actions and omissions of Defendants alleged herein are uncured or incurable deceptive acts under The Act to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising. Defendants' above-referenced actions and omissions continue to this day.

157. Defendants had actual knowledge of the defective and dangerous condition of the Defendants' pelvic mesh products and failed to take any action to cure such defective and dangerous conditions.

158. Plaintiff and the medical community relied and continue to rely upon Defendants' misrepresentations and omissions in determining which product and/or procedure to undergo and/or perform.

159. Defendants' deceptive, unconscionable or fraudulent representations and material omissions to patients, physicians and consumers, constituted unfair and deceptive acts and practices.

160. By reason of the unlawful acts engaged in by Defendants, and as a direct and proximate result thereof, Plaintiff has suffered ascertainable losses and damages.

161. As a direct and proximate result of Defendants' violations of The Act, Plaintiff

has sustained economic losses, injuries and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

162. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request restitution and disgorgement of profits, together with interest, cost of suit, attorneys' fees, and all such other and further relief as this Court deems just and proper.

COUNT XIV
GROSS NEGLIGENCE

163. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

164. Defendants' conduct was willful and wanton, showing an utter indifference to or conscious regard for the safety of others, the public and Plaintiff for which the law would allow, and which Plaintiff will seek the imposition of punitive damages, in that Defendants' conduct, when viewed objectively from Defendants' standpoint at the time of the conduct, involved an extreme degree of risk, considering the probability and magnitude of the potential harm to others, and Defendants were actually, subjectively aware of the risk involved, but nevertheless proceeded with conscious indifference to the rights, safety, or welfare of others; or included a material representation that was false, with Defendants, knowing that it was false or with reckless disregard as to its truth and as a positive assertion, with the intent that the representation was acted on by Plaintiff.

165. Plaintiff relied on the representation and suffered injury as a proximate result of this reliance.

166. Plaintiff therefore will seek to assert claims for punitive damages in an amount within the jurisdictional limits of the Court.

167. Plaintiff also alleges that the acts and omissions of named Defendants, whether taken singularly or in combination with others, constitute gross negligence that proximately caused the injuries to Plaintiff. In that regard, Plaintiff will seek punitive damages in an amount that would punish Defendants for their conduct and which would deter other manufacturers from engaging in such misconduct in the future.

168. WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XV
UNJUST ENRICHMENT

169. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

170. Defendants are, and at all times relevant, were the manufacturers, sellers, and/or suppliers of the Defendants' pelvic mesh products.

171. Plaintiff paid for the Defendants' pelvic mesh product for the purpose of treatment of stress urinary incontinence.

172. Defendants have accepted payment by Plaintiff and others on Plaintiff's behalf for the purchase of the Defendants' pelvic mesh products.

173. Plaintiff has not received the safe and effective medical device for which she paid.

174. It would be inequitable for Defendants to keep this money since Plaintiff did not in fact receive a safe and effective medical device, as represented by Defendants.

175. WHEREFORE, Plaintiff demands judgment against Defendants, and each of

them, individually, jointly, severally and in the alternative, and request compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

COUNT XVI
PUNITIVE DAMAGES

176. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein.

177. Defendants sold their products to the healthcare providers of the Plaintiff and other healthcare providers in the state of Louisiana and throughout the United States without doing adequate testing to ensure that the products were reasonably safe for implantation in the female pelvic area.

178. Defendants sold the products to the Plaintiff's health care providers and other health care providers in the state of Louisiana and throughout the United States despite their knowledge that the products can shrink, disintegrate and/or degrade inside the body, and cause the other problems heretofore set forth in this Complaint, thereby causing severe and debilitating injuries suffered by the Plaintiff and numerous other women.

179. Defendants ignored reports from patients and health care providers throughout the United States and elsewhere of the products' failures to perform as intended, which resulted in the severe and debilitating injuries suffered by the Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the products' designs or the processes by which the products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the products as safe and effective.

180. Defendants ignored medical literature, studies, and communications and reports

from their own key opinions leaders, experts, employees, agents, and representatives, of the products' failures to perform as intended, which resulted in the severe and debilitating injuries suffered by the Plaintiff and numerous other women. Rather than doing adequate testing to determine the cause of these injuries, or to rule out the products' designs or the processes by which the products are manufactured as the cause of these injuries, Defendants chose instead to continue to market and sell the products as safe and effective.

181. Defendants knew the products were unreasonably dangerous in light of their risks of failure, pain and suffering, loss of life's enjoyment, remedial surgeries and treatments in an effort to cure the conditions proximately related to the use of the products, as well as other severe and personal injuries which were permanent and lasting in nature.

182. Defendants withheld and continue to withhold material information from the medical community and the public in general, including the Plaintiff, regarding the safety and efficacy of the products.

183. Defendants knew and recklessly disregarded the fact that the products caused debilitating and potentially life altering complications with greater frequency than feasible alternative methods and/or products used to treat pelvic organ prolapse and stress urinary incontinence.

184. Defendants misstated and misrepresented data and continue to misrepresent data so as to minimize the perceived risk of injuries caused by the products.

185. Notwithstanding the foregoing, Defendants continue to aggressively market the products to consumers, without disclosing the true risks associated with the products.

186. Defendants knew of the products' defective and unreasonably dangerous nature, but continued to manufacture, market, distribute and sell the products so as to

maximize sales and profits at the expense of the health and safety of the public, including the Plaintiff.

187. Defendants continue to conceal and/or fail to disclose to the public, including the Plaintiff, the serious complications associated with the use of the products to ensure continued and increased sales of the products.

188. Defendants' acts were willful and wanton and proximately caused injury to the Plaintiff, thereby justifying an award of punitive damages.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendants, and each of them, individually, jointly and severally and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

A. compensatory damages to Plaintiff for past, present, and future damages, including, but not limited to, pain and suffering for severe and permanent personal injuries sustained by Plaintiff, health and medical care costs, together with interest and costs as provided by law;

B. restitution and disgorgement of profits;

C. reasonable attorneys' fees;

D. the costs of these proceedings;

E. economic damages;

F. medical monitoring damages;

G. punitive damages; and

H. such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

Dated: March 19, 2021

Respectfully submitted,

By: */s/ William Hawal*
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